establish special controls, including performance standards, postmarket surveillance, patient registries, guidelines, and other appropriate actions it believes necessary to provide reasonable assurance of the safety and effectiveness of the device. The special control guidance serves to support the reclassification from class III to class II of the automated blood cell separator device operating on a centrifugal separation principle intended for the routine collection of blood and blood components as well as the special control for the automated blood cell separator device operating on a filtration separation principle intended for the routine collection of blood and blood components reclassified as class II (§ 864.9245 (21 CFR 864.9245)).

For currently marketed products not approved under the premarket approval process, the manufacturer should file with FDA, for 3 consecutive years, an annual report on the anniversary date of the device reclassification from class III to class II or on the anniversary date of the 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360) clearance. Any subsequent change to the device requiring the submission of a premarket notification in accordance with section 510(k) of the FD&C Act should be included in the annual report. Also, a manufacturer of a device determined to be substantially equivalent to the centrifugal or filtration-based automated cell separator device intended for the routine collection of blood and blood components should comply with the same general and special controls.

The annual report should include, at a minimum, a summary of anticipated and unanticipated adverse events that have occurred and that are not required to be reported by manufacturers under Medical Device Reporting (MDR) (part 803 (21 CFR part 803)). The reporting of adverse device events summarized in an annual report will alert FDA to trends or clusters of events that might be a safety issue otherwise unreported under the MDR regulation.

Reclassification of this device from class III to class II for the intended use of routine collection of blood and blood components relieves manufacturers of the burden of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by reducing the burden. Although the special control guidance recommends that manufacturers of these devices file with FDA an annual report for 3 consecutive years, this would be less burdensome than the current postapproval requirements under part 814, subpart E (21 CFR part 814, subpart E), including the submission of periodic reports under § 814.84.

Collecting or transfusing facilities and manufacturers have certain responsibilities under Federal regulations. For example, collecting or transfusing facilities are required to maintain records of any reports of complaints of adverse reactions (21 CFR 606.170), while the manufacturer is responsible for conducting an investigation of each event that is reasonably known to the manufacturer and evaluating the cause of the event (§ 803.50(b)). In addition, manufacturers of medical devices are required to submit to FDA individual adverse event reports of death, serious injury, and malfunctions (§ 803.50).

In the special control guidance document, FDA recommends that manufacturers include in their three annual reports a summary of adverse reactions maintained by the collecting or transfusing facility, or similar reports of adverse events collected, in addition to those required under the MDR regulation. The MedWatch medical device reporting code instructions (*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm106737.htm*) contains a comprehensive list of adverse events associated with device use, including most of those events that we recommend summarizing in the annual report.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Reporting activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Annual Report | 4 | 1 | 4 | 5 | 20 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on FDA records, there are approximately four manufacturers of automated blood cell separator devices. The estimated average burden per response is based on the time that the manufacturers will spend preparing and submitting the annual report.

Other burden hours required for § 864.9245 are reported and approved under OMB control number 0910–0120 (premarket notification submission 501(k), 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR, part 803).

Dated: January 23, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–01626 Filed 1–28–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–1048]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Labeling Regulations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by March 2, 2015.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0485. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food

and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Medical Device Labeling Regulations—21 CFR 800, 801, and 809 (OMB Control Number 0910–0485)—Extension**

Section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded and subject to a regulatory action. Certain provisions under section 502 require manufacturers, importers, and distributors of medical devices to disclose information about themselves or the devices on the labels or labeling for the devices.

Section 502(b) of the FD&C Act requires that for packaged devices, the label must bear the name and place of business of the manufacturer, packer, or distributor as well as an accurate statement of the quantity of the contents. Section 502(f) of the FD&C Act requires that the labeling for a device must contain adequate directions for use. FDA may, however, grant an exemption if the Agency determines that the adequate directions for use labeling requirements are not necessary for the particular case as it relates to protection of the public health.

FDA regulations under parts 800, 801, and 809 (21 CFR parts 800, 801, and 809) require disclosure of specific information by manufacturers, importers, and distributors of medical devices about themselves or the devices, on the label or labeling for the devices, to health professionals and consumers. FDA issued these regulations under the authority of sections 201, 301, 502, and 701 of the FD&C Act (21 U.S.C. 321, 331, 352, and 371). Most of the regulations under parts 800, 801, and 809 are derived from requirements of section 502 of the FD&C Act, which provides, in part, that a device shall be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the device, is false or misleading in any particular way, or fails to contain adequate directions for use.

*Recordkeeping Burden*

Section 801.150(a)(2) establishes recordkeeping requirements for manufacturers of devices to retain a copy of the agreement containing the specifications for the processing, labeling, or repacking of the device for 2 years after the shipment or delivery of the device. Section 801.150(a)(2) also requires that the subject respondents make copies of this agreement available for inspection at any reasonable hour to any officer or employee of the Department of Health and Human Services (HHS) who requests them.

Section 801.410(e) requires copies of invoices, shipping documents, and records of sale or distribution of all impact resistant lenses, including finished eyeglasses and sunglasses, be maintained for 3 years by the retailer and made available upon request by any officer or employee of FDA or by any other officer or employee acting on behalf of the Secretary of HHS.

Section 801.410(f) requires that the results of impact tests and description of the test method and apparatus be retained for a period of 3 years.

Section 801.421(d) establishes requirements for hearing aid dispensers to retain copies of all physician statements or any waivers of medical evaluation for 3 years after dispensing the hearing aid.

Section 801.430(f) requires manufacturers of menstrual tampons to devise and follow an ongoing sampling plan for measuring the absorbency of menstrual tampons. In addition, manufacturers must use the method and testing parameters described in § 801.430(f).

Section 801.435(g) requires latex condom manufacturers to document and provide, upon request, an appropriate justification for the application of the testing data from one product on any variation of that product to support expiration dating in the user labeling.

*Third-Party Disclosure Burden*

Sections 800.10(a)(3) and 800.12(c) require that the label for contact lens cleaning solutions bear a prominent statement alerting consumers of the tamper-resistant feature. Further, § 800.12 requires that packaged contact lens cleaning solutions contain a tamper-resistant feature to prevent malicious adulteration.

Section 800.10(b)(2) requires that the labeling for liquid ophthalmic preparations packed in multiple-dose containers provide information on the duration of use and the necessary warning information to afford adequate protection from contamination during use.

Section 801.1 requires that the label for a device in package form contain the name and place of business of the manufacturer, packer, or distributor.

Section 801.5 requires that labeling for a device include information on intended use as defined under § 801.4 and provide adequate directions to assure safe use by the lay consumers.

Section 801.61 requires that the principal display panel of an over-the-counter (OTC) device in package form must bear a statement of the identity of the device. The statement of identity of the device must include the common name of the device followed by an accurate statement of the principal intended actions of the device.

Section 801.62 requires that the label for an OTC device in package form must bear a statement of declaration of the net quantity of contents. The label must express the net quantity in terms of weight, measure, numerical count, or a combination of numerical count and weight, measure, or size.

Section 801.109 establishes labeling requirements for prescription devices, in which the label for the device must describe the application or use of the device and contain a cautionary statement restricting the device for sale by, or on the order of, an appropriate professional.

For prescription by a licensed practitioner, § 801.110 establishes labeling requirements for a prescription device delivered to the ultimate purchaser or user. The device must be accompanied by labeling bearing the name and address of the licensed practitioner, directions for use, and cautionary statements, if any, provided by the order.

Section 801.150(e) requires a written agreement between firms involved when a nonsterile device is assembled or packaged with labeling that identifies the final finished device as sterile, for which the device is ultimately introduced into interstate commerce to an establishment or contract manufacturer to be sterilized. When a written agreement complies with the requirements under § 801.150(e), FDA takes no regulatory action against the device as being misbranded or adulterated. In addition, § 801.150(e) requires that each pallet, carton, or other designated unit be conspicuously marked to show its nonsterile nature when introduced into interstate commerce and while being held prior to sterilization.

Section 801.405(b)(1) provides for labeling requirements for articles, including repair kits, re-liners, pads, and cushions, intended for use in temporary repairs and refitting of dentures for lay persons. Section 801.405(b)(1) also requires that the labeling contain the word ''emergency'' preceding and modifying each

indication-for-use statement for denture repair kits, and the word ''temporary'' preceding and modifying each indication-for-use statement for re-liners, pads, and cushions.

Section 801.405(c) provides for labeling requirements that contain essentially the same information described under § 801.405(b)(1). The information is intended to enable a lay person to understand the limitations of using OTC denture repair kits and denture re-liners, pads, and cushions.

Section 801.420(c)(1) requires that manufacturers or distributors of hearing aids develop a user instructional brochure to be provided by the dispenser of the hearing aid to prospective users. The brochure must contain detailed information on the use and maintenance of the hearing aid.

Section 801.420(c)(4) establishes requirements that the user instructional brochure or separate labeling provide for technical data elements useful for selecting, fitting, and checking the performance of a hearing aid. In addition, § 801.420(c)(4) provides for testing requirements to determine that the required data elements must be conducted in accordance with the American National Standards Institute's (ANSI) ''Specification of Hearing Aid Characteristics,'' ANSI S3.22–1996 (ASA 70–1996), (Revision of ANSI S3.22–1987), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

Section 801.421(b) establishes requirements for the hearing aid dispenser to provide prospective users with a copy of the user instructional brochure along with an opportunity to review comments, either orally or by the predominant method of communication used during the sale.

Section 801.421(c) establishes requirements for the hearing aid dispenser to provide a copy of the user instructional brochure to the prospective purchaser of any hearing aid upon request or, if the brochure is unavailable, provide the name and address of the manufacturer or distributor from which it may be obtained.

Section 801.430(d) establishes labeling requirements for menstrual tampons to provide information on signs, risk factors, and ways to reduce the risk of Toxic Shock Syndrome (TSS).

Section 801.430(e)(2) requires menstrual tampon package labels to provide information on the absorbency term based on testing required under § 801.430(f) and an explanation of selecting absorbencies that reduce the risk of contracting TSS.

Section 801.435(b), (c), and (h) establishes requirements for condom labeling to bear an expiration date that is supported by testing that demonstrates the integrity of three random lots of the product.

Section 809.10(a) and (b) establishes requirements that a label for an in vitro diagnostic (IVD) device and the accompanying labeling (package insert) must contain information identifying its intended use, instructions for use, lot or control number, and source.

Section 809.10(d)(1) provides that the labeling requirements for general purpose laboratory reagents may be exempt from the requirements of § 809.10(a) and (b) if the labeling contains information identifying its intended use, instructions for use, lot or control number, and source.

Section 809.10(e) provides that the labeling for ''Analytic Specific Reagents'' (ASRs) must provide information identifying the quantity or proportion of each reagent ingredient, instructions for use, lot or control number, and source.

Section 809.10(f) provides that the labeling for OTC test sample collection systems for drugs of abuse must include information on the intended use, specimen collection instructions, identification system, and information about use of the test results. In addition, § 809.10(f) requires that this information be in language appropriate for the intended users.

Section 809.30(d) requires that advertising and promotional materials for ASRs include the identity and purity of the ASR and the identity of the analyte.

Section 1040.20(d) (21 CFR 1040.20) provides that manufacturers of sunlamp products and ultraviolet lamps are subject to the labeling regulations under part 801.

The burden estimates are based on FDA's current registration and listing data and shipment information.

In the **Federal Register** of August 01, 2014 (79 FR 44782), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Activity/21 CFR Section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| Processing, labeling, or repacking agreement—801.150(a)(2) | 4,870 | 739 | 3,598,930 | 0.50 | 1,799,465 |
| Impact resistant lenses; invoices, shipping documents, and records of sale or distribution—801.410(e) and (f) | 1,136 | 924,100 | 27,723,000 | 0.0008 | 22,178 |
| Hearing aid records—801.421(d) | 10,000 | 160 | 1,600,000 | 0.25 | 400,000 |
| Menstrual tampons, sampling plan for measuring absorbency—801.430(f) | 22 | 8 | 176 | 80 | 14,080 |
| Latex condoms; justification for the application of testing data to the variation of the tested product—801.435(g) | 63 | 6 | 378 | 1 | 378 |
| Total | | | | | 2,236,101 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

| Activity/21 CFR section | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|---|---|---|---|---|
| Contact lens cleaning solution labeling—800.10(a)(3) and 800.12(c) | 17 | 8 | 136 | 1 | 136 |
| Liquid ophthalmic preparation labeling—800.10(b)(2) | 17 | 8 | 136 | 1 | 136 |
| Manufacturer, packer, or distributor information—801.1 | 13,780 | 7 | 96,460 | 1 | 96,460 |
| Adequate directions for use—801.5 | 6,657 | 6 | 39,942 | 22.35 | 892,704 |
| Statement of identity—801.61 | 6,657 | 6 | 39,942 | 1 | 39,942 |
| Declaration of net quantity of contents—801.62 | 6,657 | 6 | 39,942 | 1 | 39,942 |
| Prescription device labeling—801.109 | 7,558 | 6 | 45,348 | 17.77 | 805,834 |
| Retail exemption for prescription devices—801.110 | 30,000 | 667 | 20,010,000 | 0.25 | 5,002,500 |
| Processing, labeling, or repacking; non-sterile devices—801.150(e) | 377 | 34 | 12,818 | 4 | 51,272 |
| Labeling of articles intended for lay use in the repairing and/or refitting of dentures—801.405(b)(1) | 31 | 1 | 31 | 4 | 124 |
| Dentures; information regarding temporary and emergency use—801.405(c) | 31 | 1 | 31 | 4 | 124 |
| Labeling requirements for hearing aids—801.420(c)(1) | 86 | 12 | 1,032 | 40 | 41,280 |
| Technical data for hearing aids—801.420(c)(4) | 86 | 12 | 1,032 | 80 | 82,560 |
| Hearing aids, opportunity to review user instructional brochure—801.421(b) | 10,000 | 160 | 1,600,000 | 0.30 | 480,000 |
| Hearing aids, availability of user instructional brochure—801.421(c) | 10,000 | 5 | 50,000 | 0.17 | 8,500 |
| User labeling for menstrual tampons—801.430(d) | 22 | 8 | 176 | 2 | 352 |
| Menstrual tampons, ranges of absorbency—801.430(e)(2) | 22 | 8 | 176 | 2 | 352 |
| User labeling for latex condoms—801.435(b), (c), and (h) | 63 | 6 | 378 | 100 | 37,800 |
| Labeling for IVDs—809.10(a) and (b) | 1,700 | 6 | 10,200 | 80 | 816,000 |
| Labeling for general purpose laboratory reagents—809.10(d)(1) | 300 | 2 | 600 | 40 | 24,000 |
| Labeling for analyte specific reagents—809.10(e) | 300 | 25 | 7,500 | 1 | 7,500 |
| Labeling for OTC test sample collection systems for drugs of abuse testing—809.10(f) | 20 | 1 | 20 | 100 | 2,000 |
| Advertising and promotional materials for ASRs—809.30(d) | 300 | 25 | 7,500 | 1 | 7,500 |
| Labeling of sunlamp products—1040.20(d) | 30 | 1 | 30 | 10 | 300 |
| Total | | | | | 8,437,318 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 23, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–01668 Filed 1–28–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0509]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by March 2, 2015.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0566. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002 *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Appeals of Science-Based Decisions Above the Division Level at CVM—21 CFR 10.75 (OMB Control Number 0910–0566—Revision)

Respondents: Respondents to this collection of information are applicants that wish to submit a request for review of a scientific dispute.

The Center for Veterinary Medicine's (CVM's) guidance for industry #79 entitled ''Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine,'' describes the process by which CVM formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training, or experience to be understood and resolved. Further, the